REMARKS

Status of the Claims

Claims 1, 2, 4-6, 14, 15, 27-32, 37, and 109 are pending in the present application. Claims 1 and 109 have been amended herein. Entry of the claim amendments is respectfully requested as the amendments place the claims in better form for consideration on appeal.[1]

Amendments to the Claims

Claim 1 has been amended herein to recite "an acetabular liner releasably engaging an acetabular cup of a hip replacement prosthesis for permanent mounting to the patient's pelvis; and a semiannular augment to be mounted to a rim of the acetabular liner, wherein the semiannular augment . . . ."

Claim 109 has been amended herein to recite "an acetabular liner for receiving a femoral head component of a femoral prosthesis, the acetabular liner releasably engaging an acetabular cup for permanent mounting to an acetabulum of a subject."

Claim Rejections Under 35 U.S.C. § 101

Claim 109 stands rejected under 35 U.S.C. § 101 as allegedly being directed to non-statutory subject matter. In particular, the final Office action asserts that "[c]laim 109 positively claims the acetabular cup which is mounted to the acetabulum of the subject; this positively claims the acetabulum." It is respectfully submitted that the amendments to claim 109 overcome this rejection. Accordingly, withdrawal of the rejection of claim 109 under 35 U.S.C. § 101 is respectfully requested.

Claim Rejections Under 35 U.S.C. § 112 ¶ 2

Claims 1, 2, 4-6, 14, 15, 27-32, 37-39, and 109 stand rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicant respectfully traverses these rejections.

[1] 37 C.F.R. § 1.116(b)(2).

The final Office action states:

> Regarding claim 1, "*wherein the augment material is formulated not to transform into scar tissue*" is still ambiguous. The paragraph before claims, "*wherein the augment material is supplemented with at least one of an agent to promote the formation of scar tissue*".[2]

Similarly, the final Office action states:

> Regarding claims 1, 27 and 29, "*wherein the augment is formulated not to transform into scar tissue*" is indefinite. Note that each claim allows the augment to be a biologically absorbable material. Why does applicant's augment, made from the same material, not transform into scar tissue?[3]

Applicant respectfully submits that each pending claim is definite in accordance with 35 U.S.C. § 112, second paragraph.

The final Office action appears to conflate two distinct characteristics of the augment materials: (1) whether the augment material is formulated not to transform into scar tissue and (2) whether the augment material is biologically absorbable. First, a material that is biologically absorbable does not necessarily transform into scar tissue. Second, an augment material that "is supplemented with at least one of an agent to promote the formation of scar tissue" does not mandate that the augment material itself transforms into scar tissue. Simply put, promoting the formation of scar tissue and transforming into scar tissue are distinct characteristics. Stated another way, a material may promote the formation of scar tissue without transforming into scar tissue.

Applicant's claims require an augment material that "is formulated not to transform into scar tissue" and that "is supplemented with at least one of an agent to promote the formation of scar tissue." Thus, Applicant's claims properly particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

[2] Final Office action page 4.
[3] Final Office action page 4.

Reconsideration and withdrawal of the rejection of claims 1, 2, 4-6, 14, 15, 27-32, 37, and 109 under 35 U.S.C. § 112, second paragraph, are respectfully requested.[4]

Claim Rejections Under 35 U.S.C. § 112 ¶ 1

Claims 1, 2, 4-6, 14, 15, 27-32, 37, 109, and 110 stand rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement because, allegedly, "[t]he claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention."[5] Applicant respectfully traverses these rejections.

Specifically, the final Office action asserts that the element of claim 1 reciting "wherein the augment is formulated not to transform into scar tissue" is new matter and states that "[t]he specification does not support a material that does not transform into scar tissue but contains an agent to promote scar tissue."[6]

First, Applicant respectfully asserts that the Examiner has not made the required showing and, thus, has not overcome the presumption that the description is adequate. Notably, M.P.E.P. § 2163.04 states:

> A description as filed is presumed to be adequate, unless or until sufficient evidence or reasoning to the contrary has been presented by the examiner to rebut the presumption. See, e.g., *In re Marzocchi*, 439 F.2d 220, 224, 169 USPQ 367, 370 (CCPA 1971). The examiner, therefore, must have a reasonable basis to challenge the adequacy of the written description. The examiner has the initial burden of presenting by a preponderance of evidence why a person skilled in the art would not recognize in an applicant's disclosure a description of the invention defined by the claims. *Wertheim*, 541 F.2d at 263, 191 USPQ at 97.[7]

[4] Claims 38 and 39 were withdrawn from consideration in 2005; thus, these claims are not properly rejected. The final Office action does not provide any discussion of the basis for the rejection of claim 109 under 35 U.S.C. § 112 ¶ 2; however, the above remarks are applicable to the rejection of claim 109, assuming that claim 109 is rejected under § 112 ¶ 2 for the same reasons as claims 1 and 27.
[5] Final Office action page 5.
[6] Final Office action page 5.
[7] M.P.E.P. § 2163.04 (emphasis added).

Regarding claim 1, the entirety of the final Office action's showing is the conclusory statement: "The specification does not support a material that does not transform into scar tissue but contains an agent to promote scar tissue."[8] Regarding claims 27 and 29, the entirety of the final Office action's showing is the conclusory statement: "Regarding claims 27 and 29, 'wherein the augment is formulated not to transform into scar tissue' is new matter."[9] It is beyond reasonable argument that neither of these statements properly satisfies the Examiner's "initial burden of presenting by a preponderance of evidence why a person skilled in the art would not recognize in an applicant's disclosure a description of the invention defined by the claims."[10] Thus, the rejections of claims 1, 2, 4-6, 14, 15, 27-32, 37, 109, and 110 under 35 U.S.C. § 112, first paragraph, should be withdrawn.

Second, this rejection is in error because the specification, as originally filed, supports the relevant claim limitations. At least paragraphs [0025]-[0027], [0029]-[0030], [0039]-[0043] of the specification as originally filed discuss in detail various materials from which the augments may be constructed. Thus, at least these paragraphs clearly teach a material that "is formulated not to transform into scar tissue."

Paragraphs [0044]-[0047] of the specification as originally filed discuss in detail various materials, compositions, etc. that may be incorporated into the various materials from which the augments may be constructed.[11] As known to those of skill in the art, some of these materials, compositions, etc. may promote the formation of scar tissue. Accordingly, at least these paragraphs clearly teach at least that "the augment material

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[8] Final Office action page 5.
[9] Final Office action page 5.
[10] M.P.E.P. § 2163.04.
[11] Paragraph [0044] states that "[i]t is also within the scope of the present invention to 'load' (disburse, coat, impregnate, etc.) the biologic and/or biologically reabsorbable materials comprising the snap-on augments 26 and the male fasteners 28 with agents that could hasten or assist in tissue development, assist in clotting, and/or fight infection." Paragraph [0044] then goes on to list examples of such agents. Paragraph [0045] states that "[i]t is also within the scope of the invention to incorporate growth stimulating factors in the above exemplary embodiments incorporating biologic or biologically reabsorbable materials." Paragraph [0045] goes on to discuss various examples of such growth stimulating factors. Paragraph [0046] states that "[i]t is also within the scope of the invention to incorporate connective tissue stem cells and progenitors with biologic or biologically reabsorbable materials disclosed in the above embodiments." Paragraph [0046] goes on to discuss examples of such incorporation. Paragraph [0047] states that "[i]t is also within the scope of the invention to incorporate hematopoietic stem cells and progenitors with the biologic or biologically reabsorbable materials disclosed I the above embodiments." Paragraph [0047] goes on to discuss examples of such incorporation.

[may be] supplemented with at least one of an agent to promote the formation of scar tissue."

Further, paragraph [0040] describes, without limitation, several of the possible formulations:

> In the exemplary embodiment utilizing the biologically reabsorbable snap-on augments 26, such augments 26 could be formulated to absorbed over a relatively short period (i.e., several weeks or months) and *could also be formulated* so as to be replaced by tissue (such as scar-tissue) that would provide for long-term hip stability and, hopefully, normal motion. Such formulations of biologic materials are well known by those of ordinary skill in the art.[12]

It is clear that the augment material "could also be formulated so as to be replaced by [scar] tissue," but not necessarily so. Thus, Applicant was free to claim a material that forms scar tissue, but has instead chosen to claim material formulations that do not. Applicant respectfully asserts that at least these portions of the specification as originally-filed provide proper support for the cited claim limitations. Accordingly, withdrawal of the rejection of claims 1, 2, 4-6, 14, 15, 27-32, 37, and 109 under § 112, first paragraph is respectfully requested.[13]

Claim Rejections Under 35 U.S.C. §§ 102 and 103

Claims 1, 2, 4-6, 14, 15, 27-32, 37, and 109 stand rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by or, in the alternative, under 35 U.S.C. § 103(a) as allegedly being obvious over DE 19716051 to Klüber ("Klüber").

[12] Emphasis added.
[13] Claim 110 was canceled in the Amendment filed on October 11, 2007; thus, the rejection of claim 110 is improper. The final Office action does not provide any discussion of the basis for the rejection of claim 109 under 35 U.S.C. § 112 ¶ 1; however, the above remarks are applicable to claim 109, assuming that it is rejected under § 112 ¶ 1 for the same reasons as claims 1 and 27.

§ 102 Rejections

The rejections under § 102(b) are traversed on the ground that the Klüber reference fails to teach every element of each rejected claim as required by M.P.E.P. § 2131.[14]

The final Office action even admits that Klüber is insufficient as an anticipatory reference: "Regarding at least claim 1, however, Kuber [sic] fails to teach the augment material is supplemented with at least one of an agent to promote the formation of scar tissue, a clotting agent, and an antibacterial agent."[15]

In addition, each of the independent claims recites "wherein the augment material is formulated not to transform into scar tissue." Regarding this limitation, the final Office action states: "note Kuber [sic] and applicant teach PLLA, see at least applicant's claim 5." Although both Klüber and Applicant disclose the use of PLLA, Klüber teaches that his PLLA is "is transformed into yielding connective tissue" (which the Examiner apparently interprets to be scar tissue). In direct contrast, Applicant claims an "augment material [that] is formulated not to transform into scar tissue." Put another way, while Applicant's augment may include PLLA, it is specifically "formulated not to transform into scar tissue." Therefore, Klüber does not disclose this limitation, which is present in each of the independent claims. As such, Klüber does not anticipate any of the independent claims for at least this reason.

Further still, Klüber does not disclose other limitations of the rejected claims. For example, claim 1 requires "an acetabular liner releasably engaging an acetabular cup for permanent mounting to the patient's pelvis." Claim 27 requires "an acetabular liner" and "an acetabular cup." Claim 109 requires "an acetabular liner for receiving a femoral head component of a femoral prosthesis, the acetabular liner releasably engaging an acetabular cup for permanent mounting to an acetabulum of a subject." Thus, each of the

[14] See, e.g., M.P.E.P. § 2131, in particular the section entitled "TO ANTICIPATE A CLAIM, THE REFERENCE MUST TEACH EVERY ELEMENT OF THE CLAIM", which states that "[a] claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. Verdegaal Bros. v. Union Oil Co. of California, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987)."
[15] Final Office action page 7.

independent claims clearly requires "an acetabular liner" and "an acetabular cup." Klüber, however, discloses only a single such component, labeled "B." Accordingly, Klüber does not teach the claimed structure including the acetabular liner and the acetabular cup and, therefore, Klüber does not anticipate any of the independent claims.

Additionally, claim 27 requires an "integrated" fastener. The screws of Klüber are separate and, therefore, not integrated.

For at least these reasons, independent claims 1, 27, and 109 are not anticipated by Klüber. Accordingly, withdrawal of the rejection of claims 1, 2, 4-6, 14, 15, 27-32, 37, and 109 under § 102(b) is respectfully requested.

§ 103 Rejections

The rejections of claims 1, 2, 4-6, 14, 15, 27-32, 37, and 109 under § 103(a) are respectfully traversed.

First, the cited combination of references fails to disclose every limitation of any of the rejected claims. Specifically, neither of the references discloses forming the augment from a material that "is supplemented with at least one of an agent to promote the formation of scar tissue, a clotting agent, and an antibacterial agent" as required by claim 1 and "wherein the augment material is formulated not to transform into scar tissue" as required by each of the independent claims. Further, the final Office action does not address either of these limitations in the § 103 rejections.[16] Thus, it appears that all of the limitations of the claims have not been properly considered.

This is directly contrary to M.P.E.P. § 2143.03, the heading of which is "All Claim Limitations Must Be Considered." As noted therein, "All words in a claim must be considered in judging the patentability of that claim against the prior art." [17] Not only is the final Office action's failure to consider these limitations contrary to the M.P.E.P.

[16] In the § 102 rejections, the final Office action notes: "Regarding at least claim 1, however, Kuber [sic] fails to teach the augment material is supplemented with at least one of an agent to promote the formation of scar tissue, a clotting agent, and an antibacterial agent." Final Office action page 7.
[17] *In re Wilson*, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970).

and binding caselaw, it also denies the Applicant a fair opportunity to respond and leaves a gaping hole in the record for appeal.[18]

Regarding claim 109, the final Office action states that "it would have been obvious to one having ordinary skill in the art to have made the augment of Kuber [sic] into multiple separate parts or sized smaller such that the surgeon could place the augment(s) only where deemed necessary for the patient introducing less foreign matter into said patients [sic] body and require a smaller incision."[19] Applicant respectfully disagrees.

The final Office action lists M.P.E.P. § 2144.04 as the basis for this assertion. M.P.E.P. § 2144.04 cites *In re Dulberg*[20] in subsection V(C), which discusses "making separable." The analysis in *In re Dulberg*, however, is clearly distinguishable from the present situation.

In re Dulberg involved a patent application and corresponding claims directed to a lipstick holder with a removable cap. The claims were rejected in view of prior art showing a lipstick holder where the cap was "press fitted" onto the holder and therefore was not manually removable. The court held that "if it were considered desirable for any reason to obtain access to the end of [the prior art's] holder to which the cap is applied, it would be obvious to make the cap removable for that purpose." Thus, *In re Dulberg* dealt with a device having two completely separate and clearly distinguishable components that were mounted to one another. In other words, *In re Dulberg* supports a conclusion of obviousness where two once-separate, now attached components are once again separated.

In contrast, the rejection of claim 109 apparently argues that it would be obvious to arbitrarily cut or otherwise artificially break into pieces the single, one-piece ring of Klüber. M.P.E.P. § 2144.04 and *In re Dulberg* do not support this assertion.

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[18] See, e.g., M.P.E.P. § 706.07 ("In making the final rejection, all outstanding grounds of rejection of record should be carefully reviewed, and any such grounds relied on in the final rejection should be reiterated. They must also be clearly developed to such an extent that applicant may readily judge the advisability of an appeal unless a single previous Office action contains a complete statement supporting the rejection.")
[19] Final Office action page 9.
[20] 289 F.2d 522, 523, 129 USPQ 348, 349 (CCPA 1961).

Further, the rationale stated in the final Office action for this allegedly obvious modification is illogical and would not have motivated one skilled in the art at the time of the invention to make such a modification. Specifically, the final Office action states that one of ordinary skill would modify the ring of Klüber so "that the surgeon could place the augment(s) only where deemed necessary for the patient introducing less foreign matter into said patients [sic] body and require a smaller incision."

The "introducing less foreign matter" argument does not hold water. The total amount of "foreign matter" implanted within the patient's body during a hip replacement operation would only be reduced by a negligible amount if the augment of Klüber was divided as suggested by the final Office action. Further, the likely need to include additional fasteners to attach the various separate components would likely have a substantial offsetting effect against any benefit gained by dividing Klüber's ring into smaller components.

The "smaller incision" argument is also a fallacy. Klüber describes a hip replacement procedure in which a hip socket is mounted to the patient's pelvis and the luxation ring is attached to the hip socket. Considering that the much larger hip socket is mounted to the patient's pelvis during the same operation in which the luxation ring is installed, reducing the size of the luxation ring by dividing it into smaller components would not reduce the size of the incision required. Quite simply, the luxation ring would not be the size-limiting component in such an operation.

Further still, Klüber teaches away from the claimed invention. As discussed above, the claims require the augment material to be formulated not to transform into scar tissue. In contrast, Klüber teaches that "[t]he resorbable luxation securing ring (A), made of the material PLLA . . . is transformed into yielding connective tissue, which reduces the risk of a luxation also over the long term."[21] Further, Klüber states that "after about 6 weeks the ring and attaching screws are transformed into flexible native connecting tissue, which provides protection against disclocations, for example in accidents or falls, even long-term."[22] Also, "The resorbability and transformation into flexible native

[21] Klüber, first page, paragraph labeled (57).
[22] Klüber, Description section.

connecting tissue also result in long-term protection against dislocations . . . ."[23] Thus, Klüber explicitly teaches that it is desirable for the ring material to transform into scar tissue and implicitly teaches that it would be less desirable if the ring does not transform into scar tissue. As the claims require the augment material to be formulated not to transform into scar tissue, Klüber teaches away from the claimed invention.

In addition, Klüber's statements regarding the transformation of the ring into scar tissue is demonstrative of the "accepted wisdom in the art" that it would be desirable for the augment material to transform into scar tissue. Applicants divergence from this accepted wisdom is further evidence of nonobviousness.[24]

For at least these reasons, the rationale set forth in the final Office action would not have motivated one of skill in the art at the time of the invention to modify Klüber to produce the device of claim 109. Accordingly, withdrawal of the rejections of claims 1, 2, 4-6, 14, 15, 27-32, 37, and 109 under § 103(a) is respectfully requested.

Conclusion

In light of the foregoing, it is respectfully submitted that claims 1, 2, 4-6, 14, 15, 27-32, 37, and 109, now pending, are patentably distinct from the references cited and are in condition for allowance. Entry of the Amendment, reconsideration of the application, and withdrawal of the rejections of record are respectfully requested.

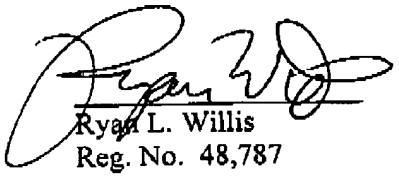
The Commissioner for Patents is hereby authorized to charge any additional fees that may be required by this paper, or to credit any overpayment to Deposit Account 50-3072.

[23] Klüber, Description section.
[24] *See, e.g.*, M.P.E.P. § 2145 ("The totality of the prior art must be considered, and proceeding contrary to accepted wisdom in the art is evidence of nonobviousness. In re Hedges, 783 F.2d 1038. 228 USPQ 685 (Fed. Cir. 1986) (Applicant's claimed process for sulfonating diphenyl sulfone at a temperature above 127°C was contrary to accepted wisdom because the prior art as a whole suggested using lower temperatures for optimum results as evidenced by charring, decomposition, or reduced yields at higher temperatures.).").

After-Final Amendment
Serial No. 10/612,784
Attorney Docket No. ORW01-GN004

In the event that the Examiner wishes to discuss any aspect of this response, please contact the undersigned at the telephone number indicated below.

Respectfully submitted,



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